

OCT 7 - 2004

3.0 510(k) Summary

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Sponsor: Synthes (USA)
1690 Russell Road
Paoli, PA 19301
(610) 647-9700

Device Name: Synthes 1.0/1.2 mm Plusdrive Screws

Classification: 21 CFR 888.3040: Smooth or Threaded Metallic Bone Fixation Fastener

Predicate Device: KLS Martin 1.0mm Center-Drive Screw System
Synthes Maxillofacial Titanium Micro Set

Device Description: The 1.0/1.2 mm Plusdrive Screws are either self-drilling or self-tapping, have a flat head profile with rounded edges with a cruciform recess, and are available in various lengths.

Intended Use: The Synthes 1.0/1.2 mm Plusdrive screws are intended for fracture fixation in hand surgery and neurosurgery.

Substantial Equivalence: Documentation is provided which demonstrates that the Synthes 1.0/1.2mm Plusdrive Screws are substantially equivalent to other legally marketed devices.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21CFR 807, Subpart E under which a device can be marketed without premarket approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.



OCT 7 - 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lisa M. Boyle
Regulatory Associate
Synthes (USA)
1690 Russell Road
Paoli, Pennsylvania 19301

Re: K042356
Trade/Device Name: Synthes (USA) 1.0/1.2 mm Plusdrive Screws
Regulation Number: 21CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 27, 2004
Received: August 31, 2004

Dear Ms Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

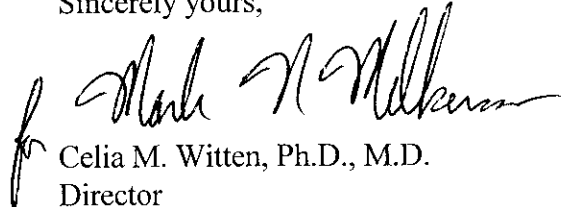
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Lisa M. Boyle

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

2.0

Indications for Use

510(k) Number (if known): K042356

Device Name: Synthes (USA) 1.0/1.2 mm Plusdrive Screws

Indications for Use:

The Synthes 1.0/1.2 mm Plusdrive Screws are intended for fracture fixation in hand surgery and neurosurgery.

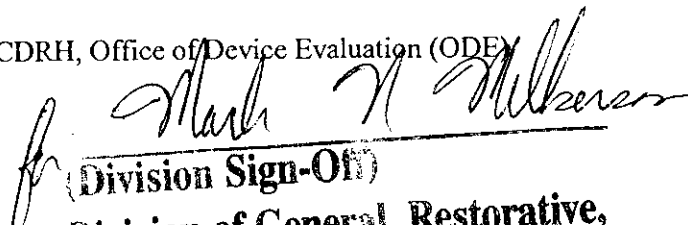
Prescription Use X
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K042356